§ 522.1720

intraperitoneally if desired. However, the results of such injections are less uniform. When given intraperitoneally, it is administered at the same dosage level as for intravenous administration. The dose must be reduced for animals showing under-nourishment, toxemia, shock and similar conditions.

- (iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 - (b) [Reserved]

[40 FR 13858, Mar. 27, 1975, as amended at 45 FR 83483, Dec. 19, 1980; 52 FR 25212, July 6, 1987; 62 FR 61625, Nov. 19, 1997; 66 FR 23588, May 9, 2001]

§522.1720 Phenylbutazone injection.

- (a) Specifications. The drug contains 100 or 200 milligrams of phenylbutazone in each milliliter of sterile aqueous solution
- (b) *Sponsors*. (1) Approval for use of the 200 milligrams per milliliter drug in dogs and horses: See sponsor Nos. 000061, 000856, 059130, and 061623 in §510.600(c) of this chapter.
- (2) Approval for use of the 200 milligrams per milliliter drug for use in horses: See sponsor Nos. 000010 and 058005 in §510.600(c) of this chapter.
- (3) Approval for use of the 100 milligrams per milliliter drug in dogs and horses: See sponsor No. 000856 in §510.600(c) of this chapter.
- (c) Conditions of use for dogs. (1) It is used for the relief of inflammatory conditions associated with the musculoskeletal system.
- (2) It is administered intravenously at a dosage level of 10 milligrams per pound of body weight daily in 3 divided doses, not to exceed 800 milligrams daily regardless of weight. Limit intravenous administration to 2 successive days. Oral medication may follow.
- (3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (d) Conditions of use for horses. (1) It is used for the relief of inflammatory conditions associated with the musculoskeletal system.
- (2) It is administered intravenously at a dosage level of 1 to 2 grams per 1,000 pounds of body weight daily in 3 divided doses, not to exceed 4 grams daily. Limit intravenous administra-

tion to not more than 5 successive days.

- (3) Not for use in animals intended for food.
- (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §522.1720, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 522.1820 Pituitary luteinizing hormone for injection.

- (a) Specifications. The drug is a lyophilized pituitary extract. Each 6-milliliter vial contains an amount equivalent to 25 milligrams of standard pituitary luteinizing hormone and is reconstituted for use by addition of 5 milliliters of 0.9 percent aqueous sodium chloride solution.
- (b) Sponsor. No. 000061 in 510.600(c) of this chapter.
- (c) Conditions of use. (1) The drug is an aid in the treatment of breeding disorders related to pituitary hypofunction in cattle, horses, swine, sheep, and dogs.
- (2) Preferably given by intravenous injection, it may be administered subcutaneously; dosage is as follows: Cattle and horses, 25 mg; swine, 5 mg; sheep, 2.5 mg, and dogs, 1.0 mg. Treatment may be repeated in 1 to 4 weeks, or as indicated.
- (3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987]

§ 522.1850 Polysulfated glycosaminoglycan.

- (a) Specifications. (1) Each 1-milliliter (mL) ampule of solution contains 250 milligrams (mg) polysulfated glycosaminoglycan.
- (2) Each mL of solution packaged in 5-mL ampules or 20-, 30-, or 50-mL vials contains 100 mg polysulfated glycosaminoglycan.
- (b) Sponsor. See No. 010797 in §510.600(c) of this chapter.
- (c) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Food and Drug Administration, HHS

- (d) Conditions of use—(1) Horses—(1) Indications for use. For the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.
- (ii) Amount—(A) Intra-articular use (carpal): 250 mg once a week for 5 weeks.
- (B) Intramuscular use (carpal and hock): 500 mg every 4 days for 28 days. (iii) Limitations. Do not use in horses
- intended for human consumption.
- (2) Dogs—(i) Indications for use. For control of signs associated with non-infectious degenerative and/or traumatic arthritis of canine synovial joints.
- (ii) Amount. 2 mg per pound of body weight by intramuscular injection twice weekly for up to 4 weeks (maximum of 8 injections).

[72 FR 56896, Oct. 5, 2007, as amended at 74 FR 67816, Dec. 21, 2009]

§ 522.1862 Sterile pralidoxime chloride.

- (a) *Chemical name*. 2-Formyl-1-methylpyridinium chloride oxime.
- (b) Specifications. Sterile pralidoxime chloride is packaged in vials. Each vial contains 1 gram of sterile pralidoxime chloride powder and includes directions for mixing this gram with 20 cubic centimeters of sterile water for injection prior to use.
- (c) Sponsor. See No. 000856 in §510.600(c) of this chapter.
- (d) Conditions of use. (1) It is used in horses, dogs, and cats as an antidote in the treatment of poisoning due to those pesticides and chemicals of the organophosphate class which have anticholinesterase activity in horses, dogs, and cats.
- (2) It is administered as soon as possible after exposure to the poison. Before administration of the sterile pralidoxime chloride, atropine is administered intravenously at a dosage rate of 0.05 milligram per pound of body weight, followed by administration of an additional 0.15 milligram of atropine per pound of body weight administered intramuscularly. Then the sterile appropriate dosage of pralidoxime chloride is administered slowly intravenously. The dosage rate for sterile pralidoxime chloride when

administered to horses is 2 grams per horse. When administered to dogs and cats, it is 25 milligrams per pound of body weight. For small dogs and cats, sterile pralidoxime chloride may be administered either intraperitoneally or intramuscularly. A mild degree of atropinization should be maintained for at least 48 hours. Following severe poisoning, a second dose of sterile pralidoxime chloride may be given after 1 hour if muscle weakness has not been relieved.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 49 FR 32061, Aug. 10, 1984]

§ 522.1870 Praziquantel injectable solution.

- (a) Specification. Each milliliter contains 56.8 milligrams of praziquantel.
- (b) Sponsors. See 000859 and 059130 in $\S510.600(c)$ of this chapter.
- (c) Conditions of use—(1) Dogs—(i) Amount. For dogs 5 pounds and under, 0.3 milliliter (17.0 milligrams); for 6 to 10 pounds, 0.5 milliliter (28.4 milligrams); for 11 to 25 pounds, 1.0 milliter (56.8 milligrams); if over 25 Pounds, 0.2 milliliter (11.4 milligrams) per 5 pounds body weight to a maximum of 3 milliliters (170.4 milligrams).
- (ii) Indications for use. For removal of canine cestodes Dipylidium caninum, Taenia pisiformis, and Echinococcus granulosus, and removal and control of canine cestode Echinococcus multilocularis.
- (iii) *Limitations*. For subcutaneous or intramuscular use; not intended for use in puppies less than 4 weeks of age; Federal law restricts the drug to use by or on the order of a licensed veterinarian.
- (2) Cats—(i) Amount. For cats under 5 pounds, 0.2 milliliter (11.4 milligrams); 5 to 10 pounds, 0.4 milliliter (22.7 milligrams); 11 pounds and over, 0.6 milliliter (34.1 milligrams) maximum.
- (ii) Indications for use. For removal of feline cestodes Dipylidium caninum and Taenia taeniaeformis.
- (iii) *Limitations*. For subcutaneous or intramuscular injection only. Not intended for use in kittens less than 6 weeks of age. Federal law restricts this